

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 25 JUN 2004

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Applicant's or agent's file reference 03104481		FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No.	International filing date (day/month/year)	Priority date (day/month/year)		
PCT/US03/07910	14 March 2003 (14.03.2003)	15 March 2002 (15.03.2002)		
International Patent Classification (IPC) or national classification and IPC				
IPC(7): A61K 31/56 and US Cl.: 514/178, 177				
Applicant				
UNIMED PHARMACEUTICALS, INC.				
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>				
Date of submission of the demand		Date of completion of this report		
14 October 2003 (14.10.2003)		27 May 2004 (27.05.2004)		
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 872-9306		Authorized officer Sreeni Padmanabhan <i>J. Roberto for</i> Telephone No. (571) 272-1600		

Form PCT/IPEA/409 (cover sheet)(July 1998)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/07910

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-176 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 177-183 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages 1-46 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
pages NONE \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig. NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims 1-42	YES
	Claims NONE	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-42	NO
Industrial Applicability (IA)	Claims 1-42	YES
	Claims NONE	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-42 meet the criteria of PCT Article 33(2) because the cited prior art does not teach the particular composition being useful in a method of treating or reducing the risk of developing a depressive disorder.

Claims 1-42 lack an inventive step under PCT Article 33(3) as being obvious over US 5,880,117 in view of WO 99/24041 and WO 96/27372.

US 5,880,117 discloses that increasing testosterone levels in a male especially after age 35 is useful in treating depression due to a slow decline in testosterone levels (see column 1, lines 6-17).

WO 99/24041 discloses that a transdermal or topical pharmaceutical composition comprising testosterone in the instant claimed amount (see page 5 lines 12-14, a penetration-enhancer such as oleic acid (a fatty acid having 17 carbon atoms see page), C1-C4 alcohol such as ethanol, 2-propanol in the instant claimed amount (see page 6 lines 6-8), and the gelling agent a polyacrylic acid in the instant claimed amount (CARBOPOL, also known as Carbomer see page 3 line 4 and page 5 line 23-24, page 6 line 29-32), is useful or has utility in treating people or mammals suffering with systemic testosterone deficient disorders (see page 14 lines 10-11). See also abstract, page 3 lines 1-5, particularly Example 1 at page 10, Example 9 at page 16, Figure 2 and claims 1-45 of Mak et al.

WO 96/27372 discloses a topical cream composition useful for treating male erectile dysfunction comprising the particular penetration enhancer, isopropyl myristate or glycerine. See abstract and claim 1 and 4.

One having ordinary skill in the art would have been motivated to employ the particular penetration composition and method of Mak and Allen, and optimize the effective amounts of the particular penetration enhancer, isopropyl myristate in the compositions in treating depression in a male in need of such a treatment.

Claims 1-42 meet the criteria of PCT Article 33(4) because the claimed methods of treating a male subject having depression has industrial applicability in the pharmaceutical art.

# PATENT COOPERATION TREATY

## PCT

### NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No. PCT/US03/07910	Applicant's or agent's file reference 03104481	Date of informal communication (day/month/year) 17 May 2004 (17.05.2004)
Applicant UNIMED PHARMACEUTICALS, INC.		

<u>Communication</u> <input checked="" type="checkbox"/> by telephone  <input type="checkbox"/> personal	<u>Participants</u> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div> <input checked="" type="checkbox"/> Applicant: UNIMED PHARMACEUTICALS, INC.  <input checked="" type="checkbox"/> Agent: BARRY, AMANDA T.  <input checked="" type="checkbox"/> Examiner(s): Shaojia Anna Jiang         </div> <div style="text-align: right;"> <input type="checkbox"/> Identity checked  <input checked="" type="checkbox"/> authorization checked  <input type="checkbox"/> personally known         </div> </div>
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Summary of communication:

In order to expedite the PCT process, Applicant's attorney gave permission to the examiner to issue the Form 408, the International Preliminary Examination Report, directly, since the due date for Form 408 (01 February 2004) have been passed.

☐ An extension of time limit is granted (Form PCT/IPEA/427).

☒ A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/429.414 § 409

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 872-9306 Form PCT/IPEA/428 (July 1992)	Authorized officer Sreeni Padmansabhan <i>J. Roberts for</i> Telephone No. (571) 272-1600
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